REMARKS

Applicants acknowledge receipt of the Office Action dated September 8, 2006 (hereinafter "the Office Action"). Reconsideration of the present application is respectfully requested in view of the foregoing amendments and the remarks which follow.

I. Status of the Claims.

Following the above amendments, claims 58-64 are pending, with claim 58 being the sole independent claim. Solely to advance prosecution, and without acquiescing to the rejections, objections or withdrawal of claims, claims 1-57 have been canceled. Claims 1-21 were previously canceled.

Claims 58-64 are new. Claim 58 is supported by canceled claim 22 and the specification at page 3, lines 20-23. Claim 59 is supported by canceled claim 23 and the specification at page 6, lines 1-4. Claim 60 is supported by canceled claims 13, 14, 32, 34 and 35 and the specification at: page 5, first paragraph; page 2, lines 18-20; and Example 4. Claims 61 and 62 are supported by canceled claims 36 and 38. Claim 63 is supported by canceled claims 39 and 41. Claim 64 is supported by canceled claim 54. Accordingly, new claims 58-64 do not constitute new matter.

II. Miscellaneous Matters.

Applicants thank the Examiner for acknowledging the claim for foreign priority and receipt of the priority document, and for review and consideration of the Information Disclosure Statement of December 28, 2004. *See* Office Action at page 1. Applicants acknowledge the Examiner's statement at page 22, § 12, that the claims are free of the prior art.

It is noted that the Examiner has not yet indicated acceptance of the drawings. Applicants respectfully request that the Examiner indicate acceptance of the drawings in the next communication.

III. The Restriction Requirement.

At § 2, pages 2-3 of the Office Action, the Examiner has made final the Restriction Requirement and withdrawn claims 25-31, 33, 42-53 and 54-57. At § 3, pages 3-5 of the Office Action, the Examiner has made final the restriction to a single peptide. Solely to advance prosecution, claims 1-57 have been canceled. Pending claims 58-64 do not contain subject matter considered by the Examiner as withdrawn and/or not corresponding to elected group or species. Accordingly, all pending claims are within the scope of that which the Examiner considers to be properly elected.

Nevertheless, Applicants maintain that they are entitled to the consideration of at least ten sequences, for reasons previously made of record. The Examiner's argument, at page 5 of the Office Action, is that the Director partially waived requirements of 37 C.F.R. § 1.141 more than 10 years ago, and that the database has increased since then, increasing the Examiner's burden. This argument is without merit on both factual and legal grounds.

As to the facts, much of the additional sequences in the databases are homologs of previously entered data. Furthermore, the Examiner ignores the great leap in bioinformatics that accompanied the growth in the number of sequences in the databases. Even a free public database like NCBI now groups sequences in a variety of ways, and link to other tools and to PubMed, greatly aiding the investigation of a sequence. Accordingly, it does not follow that the Examiner's burden has increased over the last ten years.

As to the law, the Examiner cannot merely declare that the decision of the Director of the USPTO, as published in the Federal Register, referenced and quoted in the MPEP, and on which the public has relied for a decade, is null merely because it is old. *See, The Administrative Procedures Act*, 5 U.S.C. § 551, *et seq.* A law, Federal Regulation or decision does not lapse merely because it is old. In fact, the opposite is true. A Federal Agency's decisions and interpretations of its own rules have ***enhanced***, not diminished legal force with time, as they become long-standing agency practice upon which the public has reasonably relied. *See, e.g., Air Transp. Assoc. of America v. FAA,* 169 F.3d 1, 6-9 (D.C. Cir. 1999). The Director's decision to permit examination of at least ten unrelated sequences is an example of such a long-standing agency practice, upon which the public has relied for over ten years. Reversal of such a long standing agency practice requires *at least* a new decision to be promulgated by the Director and published in the Federal Register. Indeed,

given the importance of such a change, applicants contend that the Agency should be required to go through a period of notice and comment. The Examiner has not pointed to such a new decision, nor even to any other USPTO documents or changes in the MPEP.

IV. Objections to Specification

At page 6, § 5 of the Office Action, the PTO has objected to the specification for failure to comply with 37 C.F.R. § 1.8821(a)(1) and (a)(2). Applicants have amended the specification to recite sequence identifiers, and have provided a substitute sequence listing in both paper and computer-readable form. These amendments are fully supported by the specification as filed, and do not introduce new matter. Furthermore, the paper and the disk copy are identical. 37 C.F.R. § 1.825. Applicants believe that the present application complies with 37 C.F.R. §§ 1.821-1.825, and respectfully request withdrawal of the objection.

V. Rejections Under 35 U.S.C. § 112, Second Paragraph

The following rejections have been made under 35 U.S.C. § 112, second paragraph: of claims 23 and 24 (§ 8, page 7-8) and claim 54 (§ 6, pages 6-7) for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention; and claims 32, and 34-36 (§ 7, page 7) as allegedly omitting essential steps. Applicants respectfully traverse this ground for rejection. Claims 1-57 have been canceled, and Applicants believe that the foregoing rejections do not apply to presently pending claims 58-64. Accordingly, the rejections are rendered moot. Reconsideration and withdrawal is respectfully requested.

VI. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

At page 8, claims 22-24, 32 and 34-41 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this ground for rejection.

Claims 22-24, 32 and 34-41 have been canceled and the subject matter of the canceled claims is now presented in claims 58-63. Applicants respectfully believe that rejection does not apply to presently pending claims 58-63 which are drawn, in part, to a peptide which sensitizes cells for apoptosis comprising: (a) the amino acid sequence of SEQ ID NO: 127 or

(b) an amino acid sequence which at least 90% identical to SEQ ID NO: 127 and which is capable of binding to livin-β. The present specification provides the sequence of SEQ ID NO: 127, functional characteristics and more, placing the person of ordinary skill in the art in possession of the claimed genus. Moreover, the scope of claimed genus is reasonably within that provided by the specification. Applicants respectfully request reconsideration and withdrawal of the rejections.

VII. Rejections Under 35 U.S.C. § 112, first paragraph, enablement

A. At § 10, pages 13-18, claims 32 and 34-38 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this ground for rejection.

Rejected claims 32 and 34-38 have been cancelled, and the subject matter thereof is now found in claims 60-62. Claims 60-62 are drawn, at least in part, to a method of sensitizing a livin-β-expressing cell for apoptosis, comprising administering to a livin-β-expressing cell the peptide of claim 58, optionally in combination with an intercalating agent, wherein said peptide binds to livin-β in the cell, and wherein said binding of peptide to livin-β sensitizes said cell for apoptosis. Claims 60-62 clearly define the claimed method, essential steps for performing the method, and claims a scope within that enabled by the specification. Applicants respectfully request reconsideration and withdrawal of the rejection as it may have been applied to claims 60-62.

B. At § 11, pages 18-22, claims 39-41 and 54 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this ground for rejection.

Claims 39-41 and 54 have been canceled, and the subject matter of these claims may be found in presently pending claims 63 and 64. Applicants respectfully traverse the rejection as it may have been applied to the presently pending claims.

As to claim 63, drawn to a method of treatment, the Examiner appears to recognize that the claims are enabled for *in vitro* sensitization of apoptosis in a livin-β-expressing cell, but considers that this does not enable *in vivo* methods of treatment. Applicants are not required to provide evidence of clinical or *in vivo* studies to claim methods of treatment. *See In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). Moreover, since

the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of lack of correlation between clinical efficacy and an *in vitro* or *in vivo* animal model example. *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). The Examiner presents arguments that there may not be an exact correlation between *in vitro* results and claimed *in vivo* results. However, a rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). The Examiner has not provided specific arguments why the person of ordinary skill would not consider that the data is predictive of *in vivo* efficacy. Rather, only *general* arguments are presented (*e.g.* that cell lines may be imperfect predictors) but such general arguments must contend with the fact that *in vitro* cell assays in cells lines are generally well recognized by those of ordinary skill in the art as predictive of *in vivo* efficacy in predicting cancer therapy and apoptosis. Under *Cross, id,* such general arguments are insufficient to destroy enablement.

As to the rejection of kit claims, now in pending claim 64, the Examiner accepts that SEQ ID NO: 127 binds to livin-β in a highly specific manner (*see* Office Action at page 22), but rejects kit claims based on the failure to provide a nexus between the detection of an IAP and the diagnosis of cancer. Claim 64 does not require such a nexus.

For at least the above reasons, Applicants respectfully believe that the presently pending claims are enabled and respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 5, 2007

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